



Recent Trends of Mouth Dissolving Tablet: An Overview

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ABSTRACT

The need for improved tastiness in orally administered products has expectant the development of various formulations with improved performance and acceptability. This article reviews in earlier applications and methodologies of taste masking and also highlights on the recent development techniques. Mouth dissolving tablets have increased their demand in the last decade since they rapidly disintegrate and release the drug in saliva in less than 60 seconds. The special property of mouth dissolving tablets are suitable for the pediatric, geriatric, flat on your back, mentally disabled patients and for active patients who are busy and traveling and may not have access to water. Here in this article, focused on advantages, disadvantages, main ingredients, mechanism of action of disintegration, approaches for different techniques involved in manufacturing of mouth dissolving tablet ranged from patented to non-patented technology and evaluation parameters.

Keywords: Mouth Dissolving Tablets, Superdisintegrants, Patented Technologies.

INTRODUCTION

The novel drug delivery system (NDDS) aim to improve protection and effectiveness of drug molecule by the formulating of a convenient solid dosage form for fast or ease administration and to complete better patient compliance.¹ Along with the different dosage forms developed to obtain better for the ease of administration, in the mouth dissolving tablet (MDT) is the majority generally preferred marketable products. The oral cavity is taking put for the administration of drugs because of no difficulty of administration. The administration of oral route is appropriate dosage forms like tablets, capsules, liquid formulation.² MDT's are mostly used in some serious conditions like:

MDT's are mostly used in some serious conditions like:

- Motion sickness 2
- Parkinsonism
- Pediatric and geriatric patients
- Unconsciousness
- Mentally disabled patients
- Absence of water.

To solve these problems, scientists have developed an innovative drug delivery system known as mouth dissolving tablets (MDTs).⁴ The patients can suffer the normal disintegration time of MDT from 5-30 sec.⁵ The benefits of Mouth dissolving of tablet results in quick dissolution and rapid absorption which provide a rapid onset of action. Also, drug candidates that undergo pre-gastric absorption when formulated as MDTs may show

improved oral bioavailability. It provides good stability, accurate dosing and easy manufacturing.²

Therefore, to provide the needs of such patients, recent advancements in technology have resulted in the development of viable dosage alternatives popularly known as orally disintegrating tablets (ODTs). During the past decade, the MDT (Mouth dissolving tablet) technology, which makes tablets dissolve or disintegrate in the mouth without additional water intake, has drawn a great deal of attention.³

The technology is also referred to as fast disintegrating tablets, orally disintegrating tablets, quick disintegrating tablets, fast-dissolving tablets, rapid dissolving tablets, porous tablets, quick melt tablets, and rapid melt tablets. However, of all the higher than terms United States Pharmacopeia (USP) accepted these dosage forms as ODTs. According to European pharmacopeia, these MDTs should dissolve/disintegrate is less than 3 minutes.⁴

United States Food and Drug Administration (FDA) defined as "A solid dosage form containing medicinal substances or active ingredients which disintegrates rapidly, usually within a few seconds, when placed upon tongue".⁴

Ideal Properties of MDT

MDT should have following several ideal characteristics properties:^{6,7}

1. Not require water to swallow.
2. Easily dissolve or disperse or disintegrate in the mouth within a few seconds.
3. Have an acceptable taste masking and other excipient properties.



4. Have a pleasing mouthfeel.
5. It should cost-effective.
6. Be there harder and less friable.
7. Leave minimal or no residue in mouth after administration.
8. Show signs of less sensitivity to environmental conditions like temperature, humidity etc.
9. Be there adaptable and amenable for existing processing and packaging technology.
10. Allow the produce of tablets with conventional dispensation and packaging equipment.

Drug Selection Criteria for MDDDS ^{8,9}

Suitable drug candidate for MDT should include:

1. No bitter taste.
2. Good stability in water and saliva.
3. The dose should be lower than 20mg.
4. Small to moderate molecular weight.
5. Should be partially nonionized at oral cavities.

Unsuitable drug candidate for MDT should include:

1. Drugs having very bitter taste or unacceptable taste and odor.
2. Short half-life and frequent dosing drugs.
3. Required controlled or sustained release.

Advantages of MDT ^{3,7}

1. Improved compliance / added convenience.
2. It does not need water to take the tablet.
3. The convenience of administration and accurate dosing as compared to liquids formulations.
4. It can be easily administered to pediatric, elderly, mentally disabled, and bedridden patients who have difficulty in swallowing.
5. Quick disintegration and dissolution of drug and tablet to produce fast therapeutic action.
6. No chewing needed.
7. No special set up required for the industry.
8. Bioavailability of drugs can be increased as some drugs are absorbed from mouth, pharynx, and esophagus through saliva passing down into the stomach.
9. Good mouthfeel property, especially for pediatric patients as taste masking technique is used to avoid the bitter taste of drug.
10. First pass metabolism is reduced, thus offering improved bioavailability and thus reduced dose and side effects.

11. Small packaging size.
12. There is no risk of suffocation and choking during MDT uptake.
13. Conventional processing and packaging equipments allow the manufacturing of tablets at a low cost.

Disadvantages of MDT ^{5,7}

1. The tablets usually have insufficient mechanical strength. Hence, vigilant handling is required during the formulation process.
2. The tablets may leave a disagreeable taste and/or grittiness in the mouth if not formulated properly.
3. Drugs with relatively larger doses are difficult to formulate into MDTs. e.g. Ethambutol (1000mg), Ciprofloxacin (500mg) etc.
4. Patients who concurrently take anticholinergic medications & patients may not be the best candidates for these tablet formulations.

MAIN INGREDIENTS USED IN FORMULATION OF MDT

Important ingredients that are used in the formulation of MDTs should allow quick release of the drug, resulting in earlier dissolution. Excipients balance the properties of the actives in MDT.¹⁰ The most important ingredient of MDTs includes both the active excipients. Disintegration and solubilization of a directly compressed tablet depends on the effects of disintegrate, water-soluble excipients, and effervescent agents. Mainly seen the actives and the excipients in MDT areas at least one disintegrate, a diluents, a lubricant and optionally, a swelling agent, a sweetening agent and flavorings.⁹

1. Disintegrant: Increases the rate of disintegration and hence the dissolution. E.g. Croscarmellose sodium, crospovidone, sodium starch glycolate (SSG), carboxyl methylcellulose (CMC), modified corn starch, etc.

2. Fillers: It enhances the bulk of dosage form. E.g. Mannitol, Sorbitol, Xylitol, Calcium carbonate, Magnesium carbonate, Calcium sulfate, Magnesium trisilicate, etc.

3. Surface Active Agents: It reduces interfacial tension and thus enhances the solubilization of MDTs. e.g. Sodium lauryl sulfate, Sodium dodecyl sulfate, fatty acid esters, Polyoxyethylene stearate etc.

4. Binder: It maintains the integrity of the dosage form. E.g. PVP, Polyvinylalcohol, Hydroxypropyl methylcellulose, etc.

5. Colour: It enhances the appearance and organoleptic properties of the dosage form. E.g. Sunset yellow, Red iron oxide, Amaranth, etc.

6. Flavors: It increases patient compliance and acceptability. E.g. Vanilla, Citrus oil, Fruit Essence, Eucalyptus oil, Clove oil, Peppermint oil, etc.

7. Sweeteners: They exhibit high aqueous solubility and sweetness and impart taste-masking property E.g.



Aspartame, Dextrose, Fructose, Mannitol, Sucralose, Sorbitol, Maltose, etc.

8. Lubricants: It helps reduces friction and wear by introducing a lubricating film. E.g. Stearic acid, Magnesium stearate, Zinc stearate, Talc, Polyethyleneglycol, Liquid paraffin, Colloidal silicon-dioxide, etc.^{11, 12, 13}

Role of Superdisintegrants in Mouth Dissolving Tablets

Super Disintegrants

The basic approach in the development of MDTs is the use of disintegrant. The proper choice of a suitable

disintegrant or super disintegrant in an optimum concentration somas to ensure quick disintegration and high dissolution rates it is important to the formulation development of MDT.⁹ Superdisintegrants are normally used at a small amount in the solid dosage form, typically 1–10% by weight relative to the total weight of the dosage unit. The disintegrants contain the most important function to oppose the efficiency of the tablet binder and the physical forces that act under compression to form the tablets. The stronger the binder, the more effective it must be the disintegrating agents for the tablets to release its medication.^{14, 16}

Table 1: Synthetic Superdisintegrants Used in MDT's

Synthetic Superdisintegrants	Mechanism	Effective Conc. %w/w
Cross-linked polyvinyl Pyrrolidone (Crospovidone, Kollidon®)	It is completely insoluble in water. Rapidly disperses and swells in water. Obtainable in micronized grades if needed for increasing state of dispersion in the powder blend. Swelling index - 58±1.5% v/v.	It is used in conc. of 1-3% w/w.
Sodium Starch Glycolate (Explotab and Primo gel)	Absorbs water rapidly, resulting in swelling up to 6%. It is high concentration causes gelling and loss of disintegration. Swelling index- 52±1.2% v/v.	It is used in conc. of 4-6% w/w.
Croscarmellose sodium	It is insoluble in water, although it rapidly swells to 4-8 times its innovative volume on contact with water. Specific surface area- 0.810.83 m ² /g. Swelling index- 65±1.7% v/v.	It may be used as a tablet disintegrant at conc. up to 5% w/w.

The Ideal Disintegrant:

- Poor solubility
- Poor gel formation
- Good hydration capacity
- Good molding and flow properties
- No tendency to form complexes with the drugs.

Mechanism of Action of Disintegrants

The tablet breaks to primary particles by one or more of the mechanism for tablets disintegration as listed below:

1. By swelling
 2. By capillary action
 3. Because of heat of wetting
 4. Due to release of gases
 5. By enzymatic action
 6. Due to disintegrating particle/particle repulsive force
 7. Due to disintegrating
1. **By Swelling:** When the super disintegrant comes in contact with the water/ saliva, the aqueous phase extras further adhesive force upon the super disintegrant as compared to further excipients and drug resulting in swelling and breaking apart of the tablet.⁸
 2. **Porosity and Capillary Action (Wicking):** Water then penetrates the core of the tablet, reducing the inter-particle bond thus aiding in breaking of the tablet. Thus it is termed as capillary action as slowly, the wetting rises in the tablet with the ultimate result of breakage of the tablet. The more porous the material the larger the rate of wetting and disintegration time is less.¹⁷
 3. **Air Expansion (Because of the heat of wetting):** When the disintegrants with exothermic properties get wetted, localized force in manufacture due to capillary air expansion, which helps in the disintegration of tablets.
 4. **Due to the Release of Gases:** Carbon dioxide released inside the tablets on wetting due to interaction between the bicarbonate and carbonate with citric acid or tartaric acid. The tablet disintegrates due to the manufacture of pressure inside the tablet.
 5. **By Enzymatic Reaction:** Present enzymes in the remains be there used as disintegrants. These enzymes demolish the binding action of the binder and help in disintegration. Actually, due to the swelling, weight exerted in the surface direction, it causes the tablet to disintegrate or the accelerated absorption of water leading to an enormous amplify in the volume of the granules to promote disintegration.
 6. **Due to Particle Repulsive Forces (Disintegrating Particle):** A new mechanism of disintegration attempts to clarify the swelling of the tablet completed with 'non-swellaible' disintegrants. Particle repulsion theory



proposes that no swelling particle also cause disintegration of tablets. Electric repulsive forces with particles are the mechanism of disintegration and water is needed for it.

- 7. Due to Deformation:** During the compression of the tablet, disintegrated particles get distorted particles get into their standard structure when they come in contact with water. Occasionally, the swelling capacity of starch was enhanced when granules were widely deformed during compression.¹⁰

TECHNOLOGIES USED IN PREPARATION OF MDT

Generally, two types of technologies are used in the manufacture of MDTs include:

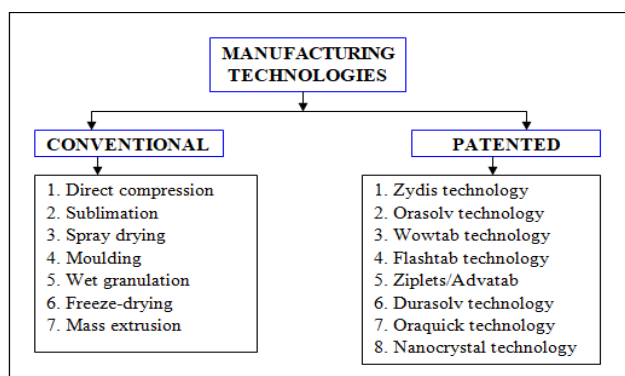


Figure 1: Technologies Used in Formulation MDTs

Conventional Techniques^{5, 21}

Freeze Drying or Lyophilization

A process, in which water is removed or sublimed from a product after it is frozen, is lyophilization or freeze-drying. Tablets obtained by this technique can be dissolved or disintegrate more rapidly than several other solid dosage forms because it will form an amorphous porous structure. This technique has shown improved absorption and bioavailability.¹⁸

Advantages:

- Lyophilization is useful for heat-sensitive drugs.
- By this technique tablets obtained dissolve more rapidly than any other solid dosage forms.
- Tablet melt fast, provides a good mouthfeel.
- Improved absorption and increased bioavailability.

Disadvantages:

- Expensive and time-consuming process.
- Essential particular packaging as obtain tablets is poorly constant and fragile.

Sublimation

The presence of porous structure in the tablet matrix is the key to the rapid disintegration of MDT. Due to the low porosity of the matrix, the tablet made from a conventional compressed method that contains a high amount of water-

soluble ingredients often dissolves quickly. Volatile ingredients are used to create the porous matrix, which further subjected to sublimation process.¹⁹

The other solvents like benzene and cyclohexane were also used to generate the porosity in the matrix.²⁰

Advantages:

- Tablets produced with good mechanical strength.
- High porosity tablets obtain and thus melt in saliva within 15 seconds.

Spray Drying

This process was used by Allen et al. for the preparation of mouth dissolving tablets. It consists of bulking agent mannitol and sodium starch glycolate or croscarmellose sodium, and crospovidone as a disintegrating agent. Addition of effervescent agent's citric acid and sodium bicarbonate results in improved dissolution and disintegration.²² Disintegration and dissolution were improved by adding together acidic substances like a citric acid or alkali substance like sodium bicarbonate.²³

Advantages:

- Supportive in the formation of highly porous and fine powder.
- Tablet created are capable of disintegrating within 20 sec after discrete in aqueous medium.²¹

Tablet Molding

Water-soluble ingredients are used in molding technique which makes tablets dissolves rapidly and completely. There are two types of tablet molding technique.

Compression Molding (Solvent method): Powder blend gets moistened with hydroalcoholic solvent and then compressed to form a wetted mass at low pressure in molded plates.

Heat method: In this technique, a drug suspension having agar and sugar (mannitol or lactose) is prepared and it is poured in the blister packaging walls which solidify at room temperature to type jelly and more kept for drying under vacuum at 30°C.²⁴

Advantages:

- This technique is simple and possible to scale up for industrial manufacture.
- As it composed of water-soluble sugars, have excellent mouth taste, and disintegrates rapidly.

Disadvantages:

- They may break while handling due to reduced mechanical strength.

Mass Extrusion

Taste masking of bitter drug granules using mass extrusion technique is the main step of this process and then tablets

are compressed using taste-masked granules and excipients including super disintegrant. These technologies involve softening the active blend by using the solvent mixture of water-soluble polyethylene glycol and methanol. Subsequent exclusion of softened mass from first to last the extruder or syringe to get a cylinder of the product into even segments using a heated blade to form tablets.²⁵

Direct Compression

Due to improved tablet excipients like disintegrants and some sugar-based excipients, this technology is now used for mouth dissolving tablets of disintegrants leads to quick disintegration and also improves the dissolution.

The evolution of carbon dioxide as a disintegrating mechanism forms the basis of another direct compression (DC) based on technology is called as ORASOLV. Individual processes describe the use of alginic acid and a water-soluble metal, carbonic acid to compress tablets.²⁶ Tablets prepared by direct compression mainly affect the dissolution and disintegration process of the tablet. By different concentrations of disintegrants tablet disintegration time can be optimized. The tablet disintegrants concentration is inversely proportional to tablet disintegration time. By incorporating effervescent disintegrating agents, mouth dissolving tablets can also be achieved, which will generate the carbon dioxide. Hence, the use of sugar-based excipients, e.g. fructose, dextrose, maltose, sorbitol, starch, etc, is another approach to prepare the MDT by direct compression.²⁷

Advantages:

- Less time of processing and lower energy is used.
- It is the low manufacturing cost of a conventional tablet.
- It is less sensitive to heat or moisture.
- Fewer excipients may be needed in a direct compression method.^{28, 29}

Disadvantages:

- In general, the content of the drug is limited in the order of 30% or approximately 50 mg.
- Not suitable for poorly flowing drug compounds.²⁹

Patented Techniques

Zydis Technology

Zydis technology is one new and first marketed technology of mouth dissolving tablets.³⁰ These tablets dissolved or disintegrate immediately as we keep in the mouth. The Zydis product is placed on the tongue dissolve in less than 3 seconds and also self-preserving as a too low is water content. Also, it utilizes microencapsulation with specific polymers with ion exchange resins to mask the bitter-tasting drug.³⁵ In addition to that; gums are included for preventing sedimentation of dispersed drug particles and reduction of porous units while freezing respectively. The

tablet is very lightweight and fragile, and must be dispensed in a particular blister pack.³¹

Advantages:

- The Zydis system is having fast disintegration time with enhanced bioavailability.³²
- The product is a great or large deal of hepatic metabolism.

Disadvantages:

- The process is time-consuming and high cost.
- An inadequate taste masking.
- Conventional packaging inappropriate.
- The product has a poor stability at higher temperature and humidity.

Orasolv Technology

This technique uses the concept of carbon dioxide is generated by a reaction for the formulation of components upon exposure to water or saliva in the mouth. The tablet matrix dissolves or disintegrates in a 1 minute or less, leaving coated drug powder. Dry the mixture for one hour at 50° C deplumed and again continue drying for an hour at 50°C. After drying, screened (8 mesh sieves) and drying again for an added 1 hour at 60°C.^{31, 34, 36}

Advantages:

- Tablets are compressed in low compression force; coated particles for taste masking of drug break out from fracture during compression.

Disadvantages:

- Have a less mechanical strength and fragile.
- Particular handling and packaging system essential for orasolv as these tablets are more fragile and weaker than conventional tablets.³⁶

Wow Tab Technology

This technology is patented by "Yamanouchi Pharmaceutical Co". The Wow tab in "WOW" indicates "Without Water". The WOWTAB product dissolves quickly in less than 15 seconds.³¹ It has recently been introduced into the U.S. The WOWTAB technology utilizes sugar and sugar-based excipients like saccharide e.g., mannitol.³⁵ Low moldability saccharide help in fast dissolution whereas high moldability saccharide has good binding property. The tablet shown as sufficient hardness and fast dissolution and disintegration, when put in the mouth.³⁴

Advantages:

- Tablets are having sufficient hardness and faster dissolution.
- It is suitable for both conventional bottle and blister packaging.



- The WOWTAB technology stable to the environment than other techniques.^{21, 33}

Disadvantages:

- No significant change in bioavailability of the drug.²¹

Flash Tab Technology

This technology includes granulation of excipients by wet or dry granulation method and followed by compressing into tablets.³⁷ Drug microgranules may be prepared by using conventional techniques like coacervation, extrusion spheronization, simple pan coating, and microencapsulation were used.³³ Excipients are used in granular form composed of disintegrating agents like that polyvinyl pyrrolidone or carboxymethylcellulose and swelling agents like that starch, carboxymethylated starches, etc., and directly compressible sugar are used.³⁸

The process used in this technology is the same as conventional tablet technology, and the tablet produced has good mechanical strength and disintegrates within one minute.²¹ Drug in the microcrystal produced along with further excipients in granular form are blended to compressed into the tablet.³⁹

Advantages:

- Tablets produced have good physical resistance and disintegrates in the mouth less than 60 seconds.

Zip lets/Advatab Technology

Zip lets/Advatab technology is patented by Passano con Barnago, Italy. It employs water-insoluble ingredients merged with more effective disintegrants to produce MDT with improved physical strength and optimal disintegration time at low compression force. This technology handles high drug loading and coated drug particles and does not involve special packaging, so they can be packed in the press on during blisters.

Advantages:

- The tablet is superior taste and smooth mouthfeel property.³¹

Disadvantage:

- The tablet is taste masking of unpleasant drug.⁴⁰

Durasolv Technology

This technology is the patented formulations of CIMA labs. These are the second generation mouth dissolving tablets obtained by CIMA labs. They composed of drug, filler or diluent and a lubricant. This technique tablets are prepared by using conventional tablet equipment with good rigidity.⁴⁰

Advantages:

- Suitable techniques for preparation required a low amount of drugs.

- Tablets are having high physical strength than orasolv technology.

- These can be packaged into, conventional packing like blister packs can be used.³⁴

Disadvantages:

- This technique is not appropriate for a high quantity of active ingredients as at high compression force, bitter drugs can be exposed to patient's taste buds.²¹

Oraquick Technology

Oraquick technology has been patented by K. V. S. Pharmaceuticals.²¹ KV Pharmaceutical claims its microsphere technology, known as Micro Mask, has improved taste masking property. During processing low-heat is produced, this Oraquick technique is appropriate for heat-sensitive drugs. This technique gives tablets with good taste masking and quick dissolution in a matter of seconds.⁴³

Advantages:

- Suitable for heat-sensitive drugs due to its low-heat is produced.
- Tablets produced have significant mechanical strength, fast dissolution with good taste masking.²¹

Disadvantages:

- Technology is its low mechanical strength.

Nanocrystal Technology

This technology is patented in Elan, King of Prussia.⁴⁵ Nanocrystal technology consists of lyophilization of colloidal dispersions of drug substance and water-soluble ingredients sealed or jam-packed into blister pockets. This method avoids manufacturing system such as granulation, blending, and tableting, which is more advantageous for highly potent and hazardous.⁴⁴

Advantages:

- Non-moisture sensitive substances.
- These are highly potent and hazardous method.
- Exceptional strength, enabling the use of conventional packaging equipment.
- Benefits of administered nanoparticles (<2 microns) in the form of a fast-dissolving tablet matrix.

EVALUATION OF MOUTH DISSOLVING TABLETS

Evaluation of Blends Pre-Compression^{4, 11, 47, 48}

Evaluation of blend for the following parameters to be carried out before compression of MDT's.

1. Bulk Density: The Powder weighing 10 g is placed into 100 ml in a measuring cylinder. The volume occupied by the powder is noted without disturbing the cylinder and bulk density is calculated by the following formula:



\therefore Bulk density = Weight of Powder / Volume of Powder

2. Tapped Density: The Powder weighing 10 g is placed into 100 ml in a measuring cylinder. The cylinder is then subjected to a fixed number of taps (~100 times) until the powder bed volume had reached the minimum level. The final volume is recorded and the tap density is calculated by the following formula:

\therefore Tapped Density = Weight of Powder / Volume of Tapped Powder

3. Compressibility Index (%): The compressibility of the blends is determined by the compressibility index. The compressibility of the drug is calculated by using the following formula:⁴⁸

\therefore Compressibility Index (%) = [(TD-BD) X 100 / TD]

Table 2: Relationship between % Compressibility Index and Flow Ability

Sr. No.	% Compressibility Index	Type of Flow Property
1	5-12	Excellent
2	12-16	Good
3	18-21	Fair to Passable
4	23-35	Poor
5	33-38	Very Poor
6	> 40	Very Very Poor

4. Hausner's Ratio: The Similar index to indicate the flow properties can be defined as Hausner's ratio. It is calculated by using the following formula:⁴⁸

\therefore Hausner's Ratio = Tapped Density x 100/ Bulk Density

The Hausner's ratio <1.25 – Good flow = 20% compressibility index

>1.25 – Poor flow =33% compressibility index²⁹

5. Angle of Repose (Θ): The angle of repose is determined by using the funnel method. Accurately weighed blend is taken in a funnel. The diameter of the powder cone is measured and the angle of repose is calculated using by the following formula:

$$\Theta = \tan^{-1} h/r$$

Where, 'h' is the height of the cone and 'r' is the radius of cone base respectively. The Angle of repose less than 30 ° shows the free-flowing of the material.⁴⁸

Table 3: Angle of Repose of Powder Flow Properties

Sr. No.	Angle of Repose (°)	Flow Property
1	1 < 20	Excellent
2	20 – 30	Good
3	30 – 34	Passable
4	> 34	Very Poor

6. Porosity (ϵ): The porosity of powder is defined as the ratio of void volume to the bulk volume of the packaging. The porosity of the powder is calculated using by the following formula:²⁹

$$\therefore \epsilon = V_b - V_p / V_p = 1 - V_p / V_b$$

Porosity is generally expressed in percentage and is given as:

$$\therefore \% \epsilon = (1 - V_p / V_b) \times 100$$

Evaluation of Post Compression

1. General Appearance: The universal appearance of a tablet, its visual uniqueness, and generally "elegance" is important for consumer acceptance. Includes tablets size, shape, color, odor, taste, surface texture, physical flaw and consistency and legibility of at all identifying.

2. Size and Shape: The size and shape of the tablet are dimensionally described, monitored and controlled.¹⁵

3. Thickness: The thickness of the tablet can be measured by using digital vernier calipers.

4. Hardness (Crushing Strength): The test is through as per the standard method. The hardness of three at random elected tablets from each formulation is determined by placing each tablet transversely between the two plungers of tablet hardness tester and applying pressure awaiting the tablet breaks down into two parts entirely.¹⁵ It was measured using a tablet hardness tester (Pfizer Hardness Tester).⁵¹

5. Friability: The friability of tablets using 10 tablets as a sample is measured by the mechanical strength of tablets. Roche friabilator were used to determine the % friability by following the procedure. Before weighed tablet was placed in the friabilator.⁵⁰ Tablets are rotated at 25 rpm for 4 minutes or up to 100 revolutions. The tablets are after that taken out, dedusted and reweighed. The percentage friability is calculated as given in the equation below. The weight loss should not more than 1%.⁴⁹

\therefore % Friability = (initial weight- final weight) x 100 (initial weight)

6. Wetting Time: The wetting time of the dosage form is related to the contact angle. A piece of tissue paper (12 cm X 10.75 cm) folded twice was placed in a small petri dish (ID = 6.5 cm) containing 6 ml of Sorenson's buffer pH 6.8. A tablet was placed on the surface of the paper, and the time for complete wetting was measured. The time required for water to reach the upper surface of the tablet is then recorded using a stopwatch.⁴¹

7. Dispersion Time: In dispersion time was measured by dropping a tablet in a beaker containing 10 ml of phosphate buffer pH 6.8 at 37±05°C. Three tablets from each formulation were randomly selected and the time required for complete dispersion time was measured.²⁹

8. Water Absorption Ratio: A piece of tissue paper folded twice is put on a small petri dish containing 6 ml of water.



The tablet is located on the tissue paper and allowed to completely wet. The wetted tablet is then weighted. Water absorption ratio, R is determined using the following formula:²⁹

$\therefore R = 100 \times \text{Weight of tablet after water absorption (W}_a) - \text{Weight of tablet before water absorption (W}_b) / \text{Weight of tablet after water absorption (W}_a)$.

9. Disintegration Test: The test was approved out on 6 tablets using the apparatus specified in I.P.-1996 distilled water at $37^\circ\text{C} \pm 2^\circ\text{C}$ was used as a disintegration media and the time in second is taken for complete disintegration of the tablet with no palatable mass remaining in the apparatus was measured in seconds.⁵⁰

10. Weight Variation Test: The uniformity of weight was followed by the total weight of 20 tablets from each formulation is determined and the average is calculated. The individual weight of each tablet is also determined to find out the weight variation.²⁹ The weight variation test would be a suitable method of determining the drug content uniformity.⁴⁶

Table 4: Specification for Uniformity of Weight^{29, 42}

Sr. No.	As Per USP Average Weight of Tablets (mg)	Maximum % Difference Allowed	As Per IP Average Weight of Tablets (mg)
1	130 or less	10	80 or less
2	More to less than 324	7.5	More to less than 250
3	More than 324	5	More than 250

11. Drug Content: Randomly selected 20 tablets from each formulation are weighed and powdered. The quantity of powder is 5 mg of drug accurately weighed and transferred to 100 ml volumetric flasks containing 50 ml of phosphate buffer (pH 6.8) or 0.1 N HCl solution. The flasks are shaken to mix the contents thoroughly and filtered.⁴¹ 1 ml of the filtrate is suitably diluted and drug content and absorbance of the resulting solution is observed at respective wavelength by using a double beam UV-visible spectrophotometer.⁴²

12. Dissolution Test: The dissolution study is performed by using the United States Pharmacopoeia (USP) dissolution testing apparatus (Paddle method, basket method). The dissolution test is carried out using 900 ml of 6.8 pH phosphate buffer or 0.1 N HCl, at $37 \pm 2^\circ\text{C}$ and 50 rpm. A sample (5 ml) of the solution is withdrawn from the dissolution apparatus at different time intervals (min).⁴¹ The sample are filtered, suitably diluted and analyzed at respective wavelength by using the double beam UV-visible spectrophotometer.⁴⁶

CONCLUSION

MDTs have in good health patient acceptance, compliance bioavailability and rapid onset of action and may offer improved biopharmaceutical properties, improved efficacy, and improved safety compared with conventional oral dosage forms. MDTs can be prepared in special ways and product performance depends upon the drug suitability or unsuitability and excipients selections in the delivery system. Universal works had been carried out in the development of super disintegrating agents and evaluation of new formulation procedures. Even though lots of MDTs are available, still continuous improvement and originality, this is needed to standardize the novel technology considering taste masking, quick disintegration/dissolution in the mouth, and quick release. As they have important advantages as solid dosage forms, MDTs may be developed for most of the available drugs in next to the future.

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